UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

APOTEX, INC.,	)	
	)	
Plaintiff,	)	Case Nos. 12-cv-9295, 15-cv-3695
	)	
v.	)	Judge Sharon Johnson Coleman
	)	
DAIICHI SANKYO, INC., DAIICHI SANKYO CO., LTD., and MYLAN PHARMACEUTICALS, INC.	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

This opinion addresses *Apotex, Inc., v. Daiichi Sankyo, Inc.*, No. 12-cv-9295 ("Apotex I") and *Apotex, Inc. v. Daiichi Sankyo, Inc.*, No. 15-cv-3695 ("Apotex II"), which concern plaintiff Apotex, Inc.'s ("Apotex") efforts to obtain the Food and Drug Administration's ("FDA") approval to market generic versions of the olmesartan medxoxomil based drugs Benicar and Benicar HCT, respectively. The original defendants, pharmaceutical company Daiichi Sankyo, Inc. and its parent company Daiichi Sankyo Co. Ltd. (collectively "Daiichi"), are currently the sole producer of Benicar and Benicar HCT. In connection with its applications to produce those drugs, Daiichi listed United States Patents Nos. 6,878,703 (the "703 patent") and 5,616,599 (the "599 patent") with the FDA. The intervening defendant, Mylan Pharmaceuticals, Inc., is a rival drug manufacturer with approved applications to market generic versions of Benicar and Benicar HCT once Daiichi's statutory period of market exclusivity ends. In both *Apotex I and Apotex II*, Apotex seeks a declaratory judgment of non-infringement of Daiichi's '703 patent, which would allow Apotex to bring its generic drugs to market sooner than it would otherwise be able by reducing the period of market exclusivity to which Mylan's generic versions of Benicar and Benicar HCT would otherwise be entitled. Apotex moves

this Court to grant summary judgment in its favor in both of its cases. For the following reasons, Apotex's motions for summary judgment are granted.

Background

1. Statutory Framework

The Hatch-Waxman Act (the "Act") governs the FDA's approval process for prescription drugs. The act was created to strike a balance between the policy goals of inducing drug companies to research and develop new drugs and enabling competing drug companies to bring lower-cost, generic copies of those drugs to market. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.,* 527 F.3d 1278, 1282 (Fed. Cir. 2008). Pursuant to the act, drug companies seeking to market new, previously unapproved drugs are required to file a New Drug Application ("NDA") with the FDA. 21 U.S.C. § 355. As part of the NDA process, the drug company must conduct clinical trials demonstrating the drug's safety and efficacy. *Id.* The company must also identify "all patents covering its drug or the methods of using the drug with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *Caraco Pharm. Labs., Ltd.*, 527 F.3d at 1282. Those patents are then listed by the FDA in a publication commonly known as the "Orange Book."

To encourage the development of generic drugs, the Act provides for a far simpler approval process, the Abbreviated New Drug Application ("ANDA"), for generic versions of previously approved drugs. *Caraco Pharm. Labs., Ltd.*, 527 F.3d at 1282. Under the ANDA process, a drug manufacturer is not required to conduct their own independent clinical trials so long as they can demonstrate that the generic drug is the bioequivalent to a drug with an approved NDA. 21 U.S.C. § 355(j)(2)(A). The ANDA process also requires that the drug manufacturer file one of four certifications addressing each patent listed in the "Orange Book" in relation to the previously approved drug. 21 U.S.C. § 355(j)(2)(A)(vii). Specifically, the ANDA filer must certify that either

(1) no patent information has been filed with the FDA, (2) the patent has expired, (3) the patent will expire on a particular date and approval of the ANDA should be deferred until then, or (4) that the ANDA applicant believes that the patent is invalid or that it would not be infringed by the generic drug. *Seattle Children's Hosp. v. Akorn, Inc.,* No. 10-cv-5118, 2011 U.S. Dist. LEXIS 145998 at *3 (N.D. Ill. Dec. 20, 2011) (Dow, J.). A certification that an orange-book-listed patent is invalid or is not infringed is commonly known as a "Paragraph IV" certification. Where an ANDA contains a Paragraph IV certification, the timing of approval depends on two events: whether the holder of the listed patent brings an infringement suit within 45 days of receiving notice of the ANDA filing and whether the company seeking approval was the first to file an ANDA with a paragraph IV certification for the listed patent. *Id.* at *4.

The Act provides that the filing of a Paragraph IV certification constitutes an act of patent infringement. *Caraco Pharm. Labs., Ltd.*, 527 F.3d at 1283. If the patentee or NDA holder does not bring suit within 45 days of receiving notice of a Paragraph IV filing, the FDA will approve the ANDA immediately. If the patentee or NDA holder does bring suit within 45 days, the FDA may not approve the ANDA for 30 months unless a court decides that the patent at issue is invalid or not infringed. *Seattle Children's Hosp.*, 2011 U.S. Dist. LEXIS 145998 at *4. The Act also provides that the first company to file an ANDA containing a Paragraph IV certification for a listed patent receives an one-hundred-and-eighty day period of market exclusivity during which the FDA will not approve a later-filed Paragraph IV ANDA based on the same NDA. In 2003, Congress amended the Act to provide that the 180-day exclusivity period is triggered by the first-filer's commercial marketing of its generic drug product, but that the period of exclusivity would be forfeited if a subsequent ANDA filer obtained a final judgment of invalidity or non-infringement. *Id.* at *5.

2. Factual Background

Daiichi holds approved NDAs for Benicar and Benicar HCT. In connection with both NDAs, Daiichi listed patents '599 and '703 in the FDA's Orange Book. Mylan was the first applicant to file ANDAs based on the approved NDAs for Benicar and Benicar HCT. Both of Mylan's ANDAs contained Paragraph IV certifications for patents '599 and '703.

In response to Mylan's Paragraph IV certifications, Daiichi statutorily disclaimed the '703 patent pursuant to 35 U.S.C. § 253, but initiated infringement actions based on the '599 patent opposing both ANDAs. Ultimately, both of Mylan's ANDAs were found to have infringed the '599 patent, and Mylan's Paragraph IV certifications for that patent were thus converted into Paragraph III certifications (recognizing that the ANDA infringed on a patent, and that it should not be considered until that patent expired). Mylan's ANDAs, however, retained their Paragraph IV certifications as to the '703 patent because that patent, although disclaimed, remains listed in the Orange Book.

Mylan's ANDAs therefore continue to be entitled to receive 180-day exclusivity periods under the act, initiated by the marketing of its generic drugs. 21 U.S.C. § 355(j)(5)(V)(iv). However, if a subsequent filer obtains a final judgment of invalidity or non-infringement with respect to the '703 patent, Mylan must begin marketing within 75 days or forfeit its exclusivity period. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

In the instant cases, Apotex seeks final judgments of validity and non-infringement regarding the '703 patent as applied to its Benicar and Benicar HTC ANDAs. Mylan intervened in both cases, because such judgments would potentially eliminate the exclusivity periods for Mylan's competing generic drug products

Apotex initially filed *Apotex I*, which concerns its ANDA for Benicar, in 2012. Daiichi filed a motion to dismiss *Apotex I* for lack of subject matter jurisdiction in that case, arguing that there

can be no justiciable dispute concerning a disclaimed patent that is no longer enforceable. This Court granted that motion, but was reversed by the Federal Circuit Court of Appeals, which held that Apotex's allegations established a justiciable controversy. *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356 (Fed. Cir. 2015). Both Daiichi and Mylan filed writs of certiorari to the Supreme Court challenging the Federal Circuit's decision, both of which were subsequently denied. *Daiichi Sankyo, Inc. v. Apotex, Inc.*, 136 S.Ct. 481 (2015); *Mylan Pharmaceuticals Inc. v. Apotex Inc.*, 136 S.Ct. 485 (2015). During the pendency of the appeals, Apotex filed *Apotex II*, which concerns its ANDA for Benicar HTC. Apotex now moves for summary judgment in both *Apotex I* and *Apotex II* declaring that the '703 patent is not infringed by the filing of Apotex's ANDAs. Daiichi and Mylan, in separate briefs, oppose both motions based on the previously-pending writs of certiorari. Additionally, Mylan argues that Apotex lacks standing to bring these suits. Neither defendant, however, argues that the disclaimed '703 patent is infringed by Apotex's ANDAs.

Legal Standard

Summary judgment is proper when "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). In determining whether a genuine issue of material fact exists, this Court must view the evidence and draw all reasonable inferences in favor of the party opposing the motion. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S.Ct. 242, 91 L.Ed.2d 202 (1986). However, "[m]erely alleging a factual dispute cannot defeat the summary judgment motion." *Samuels v. Wilder*, 871 F.2d 1346, 1349 (7th Cir. 1989). "The mere existence of a scintilla of evidence in support of the [non-movant's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [non-movant]." *Anderson*, 477 U.S. at 252.

Standing is "the threshold question in every federal case, determining the power of the court to entertain the suit." *Warth v. Seldin*, 422 U.S. 490, 498, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975). Under Article III, only a plaintiff with a personal stake in a case or controversy has standing. *Gonzales v. North Twp.*, 4 F.3d 1412, 1415 (7th Cir. 1993). In order to establish standing, a party must demonstrate: (1) an alleged injury in fact, a harm suffered by the plaintiff that is concrete and actual or imminent; (2) causation, a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant; and (3) redressability, a likelihood that the requested relief will redress the alleged injury. *Caraco Pharm Labs., Ltd. v. Forest Laps., Ltd.,* 527 F.3d 1278, 1291 (Fed. Cir. 2008); *see also Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). Because standing is an indispensable part of the plaintiff's case, it must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, and with the same manner and degree of evidence as is generally required at that stage of the litigation. *Lujan*, 504 U.S. at 561.

Discussion

As an initial matter, this Court notes that both Daiichi and Mylan argued that this Court should defer its ruling until after the resolution of their pending writs of certiorari appealing the Federal Circuit's decision in *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356 (Fed. Cir. 2015). Because certiorari has since been denied, this Court disregards those arguments as moot.

Mylan contends that this Court cannot grant summary judgment in Apotex's favor because Apotex has failed to present evidence demonstrating that it has standing. Mylan asserts that Apotex has failed to adduce evidence demonstrating injury-in-fact because it has not shown that it has pending ANDAs in good standing such that the listing of the 703 patent in the Orange Book serves

as a "but-for" barrier to regulatory approval and market entry.[1] Mylan further argues that Apotex has failed to demonstrate redressability because, based on evidence drawn from the public record, Mylan does not believe that Apotex would be able to obtain FDA approval to market its olmesartan drug products in the United States.

As the Federal Circuit noted in *Apotex, Inc. v. Daiichi Sankyo Co., Ltd.*, 781 F.3d at 1365, 35 U.S.C. § 271(e)(2) makes the filing of an ANDA with a paragraph IV certification an artificial act of infringement and thereby allows litigation over the underlying patent to take place well before any product entered the market and before any FDA regulatory approval, with the litigation serving to remove one barrier to the product's subsequent marketing and approval. Tentative approval, or even a strong likelihood of approval by the FDA, are not prerequisites for the resolution of this action. *See Caraco*, 527 F.3d at 1295 ("Caraco has a complete generic drug product that has been submitted to the FDA for approval, and no additional facts are required to determine whether this drug product infringes the claims of Forest's '941 patent."). Indeed, the Federal Circuit has found similar injuries to be redressible even when remaining Orange Book patents might still exclude the generic manufacturer from the drug market. *Id.* at 1293. All that is required to constitute an injury and establish redressability is showing that a patent's listing constitutes an independent barrier to entry into the drug market and that a judicial decision can remove that barrier; there is no need to show that it is the only remaining barrier to entry. *Id.* at 1292.

Here, the '703 patent's listing in the Orange Book constitutes an independent barrier to the drug market for both of Apotex's ANDAs that may be removed through a favorable decision from this Court. Because Apotex has filed ANDA's containing Paragraph IV disclaimers with respect to

[1] In its Rule 56.1 statement the only support that Apotex provided for its assertion that it had filed ANDAs for its Benicar and Benicar HTC based products was a citation to the paragraphs from its amended complaints alleging the same. Because an allegation made in a complaint cannot properly support an assertion of fact, pursuant to Federal Rule of Civil Procedure 56(e)(1) this Court gave Apotex the opportunity to supplement its Rule 56.1 statements with evidence properly supporting that assertion. Apotex subsequently filed supplemental Rule 56.1 statements demonstrating, by way of notices of receipt from the FDA, that it had filed ANDAs for both drug products.

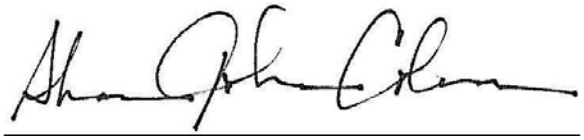
Patent '703, it has standing to ask this Court to determine whether its ANDAs would infringe upon that patent which, although disclaimed, nonetheless serves as a barrier to entry into the marketplace by virtue of its continued Orange Book listing.

Turning to the merits of Apotex's motions, it is undisputed that Daiichi disclaimed every claim under patent '703 pursuant to 35 U.S.C. § 253. Non-infringement of the '703 patent follows as a matter of law from the fact that it has been formally disclaimed. *Altoona Publix Theatres v. Am. Tri-Ergon Corp.*, 294 U.S. 477, 492, 55 S.Ct. 455, 79 L.Ed. 1005 (1935). Accordingly, Apotex's ANDAs for Benicar and Benicar HTC do not infringe on the '703 patent.

Conclusion

For the foregoing reasons, Apotex's motions for summary judgment in *Apotex I* [103] and *Apotex II* [38] are granted.

SO ORDERED.



Sharon Johnson Coleman
United States District Court Judge

DATED: January 8, 2016